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10/532,699	04/26/2005	Taro Takahashi	155-05	8736
7559 1927/2010 John F MeNulty, Esquire Paul & Paul 2000 Two Thousand Market Street Philadelphia, PA 19103			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/532.699 TAKAHASHI ET AL. Office Action Summary Examiner Art Unit Patricia A. George 1789 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 21 September 2010. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 21-23 and 25-31 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (FTO/SB/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application.

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#### DETAILED ACTION

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27, and all claims depending on it, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has submitted new claims which state "wherein the additive is not a salt." In applicant's remarks they argue that prior art requires the presence of a salt; therefore, it does not disclose all of the elements of Claims 27 – 31 (i.e. because they limit the additive to not being a salt). Applicant's disclosure does not appear to have possession of all salts, however, only appears to discuss salts which are calcium fortifiers, and salt of organic acids.

Therefore, applicant does not appear to have possession of inorganic salts, such as the magnesium chloride of the previously applied reference, and can not limit the use of a compound that they have not possessed.

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#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-23, and 25-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Lapre, in view of the combination of Takahashi and Jarvis.

Markovic is provided as evidence.

Jarvis: The polysaccharide structure of potato cell walls: Chemical fractionation; Journal: Planta, Issue: Volume 152, Number 2 / June, 1981; Received: 31 October 1979 Accepted: 2 February 1981.

Lapre teaches a cooked and hydrated carbohydrate core, such as rice, is coated with a polysaccharide coating, comprising pectin, which provides the benefit of reducing the glycemic response to make improvements such as: treatment of diabetes, hypoglycemia, and glycogen storage disease, and suppressing appetite and assisting the performance of sustained physical activity. Lapre teaches the coating is crosslinked (i.e. enhanced) so that it will remain on the surface of the carbohydrate, because polysaccharides tend to be water soluble (i.e. aqueous). See abstract and summary sections.

Lapre teaches to use crosslinkable polysaccharides to coat starch, by adding one or more cations, such as edible salts, as a catalyst to the crosslinking during cooking in an aqueous medium. See reference Summary section.

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Once the coating is crosslinked in an aqueous medium, the polysaccharides are taught to be "preferably at least essentially insoluble, or at least substantially insoluble, in boiling water".

Lapre teaches one or more water-soluble polysaccharides may be used, in combination, including: pectin and pectinic acid, which reads on water-soluble acidic polysaccharides. See bottom of column 7.

Lapre is silent as to the water-soluble acidic polysaccharides being derived from a white potato (e.g. including uronic acids), as in claim 21.

Takahashi teaches that there are many benefits from using pectin derived from white potatoes, such as:

- pectin derived from white potatoes in hot water (i.e. water soluble), are known to have a function which can stabilize proteinic distribution, see abstract and paragraph 0019;
- pectin derived from white potatoes has the benefit of maintaining its state even after heat is applied, see "Effect of the Invention";
- pectin derived from white potatoes is stronger because the starch that is contaminated during the extraction process, is desirably removed, see paragraph 0018;

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4) the extraction temperature of pectin from white potatoes is carried out in a range that speeds up extraction and therefore provides an economical advantage because the extraction can be managed in a short time, see paragraph 0017.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the method of coating starchy foods with a pectin, as Lapre, to include the specifically claimed pectin, such as white potato derived water soluble acidic polysaccharide (i.e. pectin), as claimed, because one of skill would have a reasonable expectation of success in the teaching by Takahashi, which illustrates that there are benefits in using the type of pectin derived from white potatoes, including that the pectin from white potatoes is stronger, and that it is more economical to make because the production time can be reduced due to having the capability of using increased temperatures. One of skill would be motivated to use a pectin that is stronger and is economically made, because its use would provide costs savings, such as reduced shipping cost for less volume (i.e. a stronger product), and reduced manufacturing cost, a certain benefit.

Lapre is silent as to there being uronic acids in the portion of water-soluble acidic polysaccharides.

Markovic provides evidence that pectin consists of a linear chain of  $\alpha$ -(1-4)-linked <u>D-galacturonic acid</u> (i.e. an uronic acid). See the 2<sup>nd</sup> paragraph of the introduction.

Therefore, the pectin in the modified invention of Lapre inherently has a quantity of uronic acid, which inherently exists in the said pectin of the modified invention of Lapre.

Lapre teaches the amount of coating used is relatively thin at about 0.01 to 5 wt% of the core food, however is silent as to the range of uronic acid and starch in the polysaccharide, as in claims 21-23, and 28-29.

Jarvis teaches that potato polysaccharide inherently has a range of about greater than 0 to 20 % glacturonan (i.e. uronic acid). See reference starting at Fig. 1.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the method of coating starchy foods with a potato derived water soluble acidic polysaccharide (i.e. pectin) having uronic acid, as the modified teaching of Lapre, to include the specifically claimed range of uronic acid in the polysaccharide, as Jarvis, because one in the art would have a reasonable expectation of success in the teaching by Jarvis which illustrates the inherent components of potatoes.

As to the amount of uronic acid in the coated food, since greater than about 0 to 20% of the polysaccharide is uronic acid, and the polysaccharide is about 0.01 to 5 wt% of the food, it appears that quantity of uronic acid would be from about 0.002 to 1% of the weight of the core, which is encompassed by the claim of 0.003 to 1.0 wt%, as in

claim 21; 0.035 to 0.5, as in claims 22 and 28; and 0.08 to 0.2 wt% as in claims 23 and 29.

Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 105 USPQ 223 (CCPA 1955).

As to the intended use of avoiding sticking, one of skill would have a reason to expect that similar methods, such as the one taught above, would have similar intended uses

With respect for claims 25-26, and 30-31, the modified teaching of Lapre, teaches in Takahashi, that the potato-derived water-soluble acidic polysaccharides have a starch content of about 7%, which encompasses the claim of: a starch content of no more than 60%, as in claim 21; a starch content of no more than 30%, as in claims 25 and 30; and a starch content of no more than 10%, as in claims 26 and 31. See paragraph 0024.

With respect to claim 27, the salts which are used in the reference of Lapre, are catylists, not additives and therefore do not provide the additive, as claimed.

Lapre teaches the polysaccharides are used in combination with water, which reads on the additive as claimed.

#### Response to Arguments

It is asserted, that Lapre's starting material are water-soluble however Lapre prefers that the coating of polysaccharides be insoluble in water. (Lapre, Col. 8, lines 10-11). Applicant then goes on to admit that the coating created by Lapre's process may be partially soluble, if the cations are not able to achieve complete cross-linking.

In response, as applicant admits, all of the cations are not able to achieve complete cross-linking and therefore the coating created by Lapre's process is partially soluble, Which reads on applicant's claim.

It is asserted that, applicants' invention does not include polysaccharides that are cross-linked.

In response, since applicants claim is open (.i.e. comprising), and does not exclude polysaccharides that are cross-linked, this argument is not commensurate with the scope of the claim language.

Applicant argues that because Applicants' invention does not include salt as an additive, there can be no cross-linking. Lapre requires the presence of a salt; therefore, Lapre does not disclose all of the elements of Claims 27 - 31.

Aplicant does not appear to disclose all salts, only salts of organic acids and salts that are calcium fortifiers, therefore, the reference of Lapre which relies on inorganic salts, such as magnesium chloride stands.

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The Examiner asserts that potato polysaccharides inherently have a uronic acid content of 0 to 20% and cites Figure 1 in Jarvis. The Examiner incorrectly reads the graph depicted in Figure 1. Jarvis extracted polysaccharides from 100 mg of potato cell walls by stirring it vigorously with 50 cm3 of oxalate citrate buffer and much of the polysaccharides remained in the cell walls using this extraction procedure. (Jarvis, page 96). Therefore, no final determination can be concluded as to the proportion of uronic acids in potato polysaccharides and Figure 1 provides absolutely no basis for the Examiner's conclusion that potato polysaccharides comprise 0 to 20 % uronic acids.

In response, applicant appears to be arguing that the method of measuring uronic acid in potato polysaccharides must be excluded because had an amount not been measured its content would be unknown. This argument is not persuasive because the art finds a range of uronic acid that is within applicants range to be known.

Applicant asserts that because there is no discussion on the success of using polysaccharides to improve the properties of cooked cereal foods, in the applied references, that the Examiner is applying improper hindsight reasoning.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

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reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA

1971).

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. George whose telephone number is (571) 272-5955. The examiner can normally be reached on Mon. -Wed. between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia A George Examiner Art Unit 1789

/Patricia A George/ Examiner, Art Unit 1789

/Keith D. Hendricks/ Supervisory Patent Examiner, Art Unit 1781